Notices

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 01–023N]

Codex Alimentarius Commission: Thirty-Fourth Session of the Codex Committee on Food Hygiene

AGENCY: Office of the Under Secretary for Food Safety, USDA.

ACTION: Notice of public meetings and request for comments.

SUMMARY: The Office of the Under Secretary for Food Safety, U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA), Department of Health and Human Services, are sponsoring two public meetings, on August 30 and September 25, 2001. The purpose of the meetings is to provide information and receive public comments on agenda items that will be discussed at the Thirty-fourth Session of the Codex Committee on Food Hygiene (CCFH), which will be held in Bangkok, Thailand, on October 8–13, 2001. The Under Secretary for Food Safety and FDA recognize the importance of providing interested parties the opportunity to obtain background information on the Thirty-fourth Session of the CCFH and to address items on the agenda.

DATES: The public meetings are scheduled for August 30 and September 25, 2001, from 1 p.m. to 5 p.m.

ADDRESSES: The public meetings will be held in Conference Room 1409, Federal Office Building 8, 200 C Street, SW., Washington, DC 20204. Reference documents will be available for review in the FSIS Docket Room, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th Street, SW., Washington, DC 20250–3700. The documents will also be accessible via the World Wide Web at the following address: *http://www.fao.org/waicent/faoinfo/economic/esn/codex.* Submit one original and two copies of written comments to the FSIS Docket Room and reference Docket #01–023N. All comments submitted in response to this notice will be available for public inspection in the FSIS Docket Room between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: F. Edward Scarbrough, Ph.D., U.S. Manager for Codex, U.S. Codex Office, Food Safety and Inspection Service, Room 4861, South Building, 1400 Independence Avenue SW., Washington, DC 20250–3700, Telephone (202) 205–7760; Fax (202) 720–3157. Persons requiring a sign language interpreter or other special accommodations should notify Dr. Scarbrough at the above number.

SUPPLEMENTARY INFORMATION

Background

The Codex Alimentarius Commission (Codex) was established in 1962 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Codex is the major international organization for encouraging fair international trade in food and protecting the health and economic interests of consumers. Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to ensure that the world's food supply is sound, wholesome, free from adulteration, and correctly labeled.

The CCFH was established to draft basic provisions on food hygiene for all foods. The Government of the United States hosts this Committee and will chair the Committee meeting.

Issues To Be Discussed at the Public Meeting

The following issues and referenced documents will be discussed during the public meetings:

1. Matters referred by the Codex Alimentarius Commission and other Codex committees, CX/FH 01/2.
2. Endorsement of hygiene provisions in the Codex standards and codes of practice, ALINORM 01/18 Appendix V.
3. Code of practice for fish and fish products.
4. Draft code of hygienic practice for the primary production of fresh fruits and vegetables, ALINORM 01/13A, Appendix V.
5. Report of the ad hoc expert consultation of risk assessment of microbiological hazards in food and related matters, CX/FH 01/5.
6. Proposed draft guidelines for the control of Listeria monocytogenes in foods, CX/FH 01/6.
7. Proposed draft principles and guidelines for the conduct of microbiological risk management, CX/FH 01/7.
8. Proposed draft code of hygienic practice for milk and milk products, CX/FH 01/8.
9. Proposed draft guidelines for hygienic reuse of processing water in food plants, CX/FH 01/9.
10. Proposed draft guidelines on the application of HACCP in small and/or less developed business, CX/FH 01/10.
11. Proposed draft revision of the code of hygienic practice for egg products, CX/FH 01/11.
12. Discussion paper—risk profile on the antimicrobial resistant bacteria in food, CX/FH 01/12.
13. Discussion paper on the proposed draft guidelines for the validation of food hygiene control measures, CX/FH 01/13.
14. Discussion paper on the proposed draft guidelines for evaluating objectionable matter in food, CX/FH 01/14.

Public Meeting

At the August 30th public meeting, the issues will be described, discussed, and attendees will have the opportunity to pose questions and offer comments. At the September 25th public meeting, draft United States positions on the issues will be described, discussed, and attendees will have the opportunity to pose questions and offer comments. Comments may be sent to the FSIS Docket Room (see **ADDRESSES**). Please state that your comments relate to CCFH activities and specify which issues your comments address.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it and provide copies of this **Federal Register**

publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on-line through the FSIS web page located at http://www.fsis.usda.gov. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/ stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720–5704.

Done at Washington, DC on July 31, 2001.

F. Edward Scarbrough,

U.S. Manager for Codex Alimentarius.

[FR Doc. 01–19595 Filed 8–3–01; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 00–026N]

Residue Policy

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing its intention to harmonize its procedures with those of the Food and Drug Administration (FDA) with respect to the target tissue/marker residue policy in testing animal tissues for residues of new animal drugs. FSIS has reviewed its approach regarding the disposition of carcasses containing residues and has determined that its approach is not consistent with FDA's approach. To ensure that meat containing unsafe levels of chemical residues is not being released into commerce, FSIS intends to modify its approach to testing and disposition of carcasses for violative residues to be more consistent with FDA's target tissue/marker residue policy.

DATES: Comments may be submitted by no later than September 5, 2001. FSIS will review comments and address them in another notice. That notice will announce when the procedural changes addressed in this notice are effective.

ADDRESSES: Submit one original and two copies of written comments to: FSIS Docket Clerk, Docket # 00–026N, Room 102, Cotton Annex Building, 300 12th Street, SW., Washington, DC 20250–3700. All comments received in response to this notice will be considered part of the public record and will be available for viewing in the FSIS Docket Room between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Daniel L. Lazenby, Acting Director, Technical Analysis Staff, Office Policy, Program Development and Evaluation; (202) 205–0210.

SUPPLEMENTARY INFORMATION:

Background

When a new animal drug is given to an animal, some of the parent drug and resulting metabolites remain in the animal as residues. A new animal drug is defined under 21 CFR 510.3(g) and examples of ''newness'' are specified in 21 CFR 510.3(i).

For new animal drugs approved prior to 1976, tolerances were assigned for each of the edible tissues. Collection and testing of multiple tissues is routine for these new animal drugs. As each tissue is tested, it is either released or condemned, depending on whether it is found to have an acceptable level of residue.

Since 1976, FDA has been establishing tolerance levels for new animal drugs using a ''marker residue.'' The term ''marker residue'' is defined in the Food and Drug Administration's (FDA) Center for Veterinary Medicine's Guideline, ''*General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals,*'' (CVM Guideline #3, *http://www.fda.gov/cvm/guidance/guideline3toc.html*) as being the residue selected for assay whose concentration is in a known relationship to the total residue of toxicological concern in the last tissue to deplete to its permitted concentration.

These marker residues serve as a sentinel for the levels of all residues associated with that drug (parent and metabolites) in all edible tissues of the food animal. CVM's Guideline ı3 defines target tissue as being the edible tissue selected to monitor for residues in the target animals, including, where appropriate, milk or eggs. When the FDA-approved conditions of use for a new animal drug are followed, the concentration of marker residue in the target tissue should be below the target tissue tolerance when the animal is sent to slaughter. To establish an appropriate tolerance for the marker residue, FDA must know the relationship between the concentration of the marker residue in the target tissue and the concentrations of total residues in each of the edible tissues (CVM Guideline ı3). FDA obtains this information from the drug's sponsor who, in submitting a New Animal Drug Application (NADA), includes total residue depletion and metabolism studies with radiolabeled compound in species for which approval is sought (CVM's Guideline #3). The target tissue is usually liver, kidney, or fat because residues generally deplete from these tissues more slowly than from other tissues, i.e., muscle tissue.

In those cases where FDA has established a marker residue tolerance in target tissue, when the marker residue in the target tissue depletes to a concentration equal to or less than the target tissue tolerance(based on the total residue depletion and metabolite data),it can be reliably anticipated that the concentration of total residue in each edible tissue has reached its respective permitted safe concentration. In other words, when the concentration of the marker residue is at or below its tolerance in the target tissue, the entire carcass is considered safe to eat, without additional testing of the individual edible parts of the animal carcass. Similarly, if the level of the marker residue in the target tissue exceeds the tolerance, FDA will consider the entire carcass to be adulterated, because the residue in the target tissue is imputed to the rest of the animal.

In addition, for 15 new animal drugs FDA has specifically established tolerances for residues found in muscle tissue and analytical methods for detecting those residues. Therefore, the muscle tissue may be released for human consumption if it meets the muscle residue tolerance level. This is true even when the marker residue tolerance in the target tissue has been exceeded. The target tissue, however, would be condemned. In this situation, documenting that the drug residues in muscle are less than the muscle tolerance will only demonstrate that the muscle tissue is safe, and does not imply that any other part of the animal carcass is safe, except in those few instances where muscle has been designated to be the target tissue.

FSIS Practice

FSIS regulations regarding residues state that ''* * *Animal drug residues are permitted in meat and meat food products if such residues are from drugs which have been approved by the Food